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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,810	01/23/2004	Cynthia C. Bamdad	M1015.70054US01	5010

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,810	BAMDAD ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *121-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *121-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement of April 11, 2006 [which was made by a different Examiner] is hereby withdrawn, and all the claims are hereby examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 121, 122 and 130 are rejected under 35 U.S.C. 102(e) as being anticipated by Li, 6,704,104.

Li discloses a detection system that allows for simultaneously measuring the response of multiple fluorophores from each site within an array. Li discloses that the invention involves using a spectrometer to spectrally obtain simultaneously the total fluorescence spectrum resulting from multiple fluorophores. Based on the total observed fluorescence spectrum, deconvolution techniques can be used to resolve the amount of multiple individual fluorophores in the sample. Within a given spectral range,

deconvolution techniques allow more fluorophores to be resolved than by using filters. Therefore, more samples can be multiplexed within each site of the array to increase throughput and accuracy of differential gene expression measurements. Multiplexing a group of spectrally close dyes allows more efficient excitation using a single excitation source (col. 3, lines 34-55.) Figure 6 shows the deconvolution of fluorescence intensities measured (col. 5, lines 3-4.) Li discloses providing a fluorescence detector having sufficient resolution, i.e., a sufficiently small point spread function, to measure fluorescence even from high density arrays (col. 8, lines 52-64.)

The detector may be a CCD 31 for example. Detector 31 includes a preferably rectangular array of rows and columns of pixels. A suitable light detector includes an array of light sensitive elements to sense the fluoresced light. Each light sensitive element is configured to measure an intensity of light impinging thereon (col. 9, line 60 – col. 10, line 26.)

From the detector array 31 within the camera 30, the detected intensities are sent to a processing unit, such as a personal computer 34 (col. 10, lines 27-39.) If the array of site to be illuminated is small enough that all of the sites can be arranged to fit simultaneously within the field of view of the detector, all of the sites can be illuminated by using the beam steering device to direct the excitation light sequentially to each site without having to move the sites with respect to the detector (col. 10, lines 40-59.)

Figures 4a and 4b show an embodiment to allow more than one site to be illuminated simultaneously by the excitation light. After the excitation light passes through a beam expander, it can illuminate a plurality of sites 519 at a given instant

(col. 11, line 6 – col. 12, line 14.) Alternatively, one or more beam splitters 522 may be used to separate the excitation light into a plurality of excitation beams 524. Each excitation beam 524 can be directed to illuminate a single site at any given moment. The combination of excitation beams 524, therefore, illuminates a plurality of sites simultaneously (col. 12, lines 14-31.)

Li also disclose in an exemplary embodiment that the probes are DNA strands with a specific sequence that is complimentary to a section of a target DNA sequence. One end of the DNA probe is chemically (covalently) anchored onto the surface of the solid substrate to provide a chip 300 with an array of probe nucleotides. Thus, the sites can comprise regions of the substrate that include different probes immobilized at a surface of the substrate or to a surface supported by the substrate. When the sites are treated with the sample solution containing target DNA under conditions sufficient to allow hybridization, target DNA with a section of sequence complementary to the probe will anneal to the probe. The amount of target DNA annealed to the probe site is a function of the concentration of the target DNA in the sample solution. Because the target DNA molecules are tagged with a fluorescent dye and the probes are not, the increase of fluorescence signal at each assay site indicates the target DNA concentration in the sample solution. Column 7, lines 13-33.

Thus, as to Applicant's claim 121, Li disclose exposing at least two surface regions [probes], each presenting a different chemical, biochemical or biological functionality, to a sample, determining an interaction pattern [CCD camera] of the sample with the at least two surface regions, indicative of an interaction between at

least one component of the sample with the at least two surface regions [because of the labeled target, e.g., column 7, lines 13-33.]

As to claim 122, given that detection of concentration of a target is disclosed (e.g., column 7, lines 13-33), the skilled artisan would have recognized that the method encompass detection in which there are least two components in the sample that carry identical immobilized signaling entities (i.e., identical targets in the sample tagged with identical dyes). t is noted that there is no requirement that the components be different from each other.

As to claim 130, it is also disclosed that examples of targets include antibodies, cell membrane receptors, monoclonal antibodies and antisera reactive with specific antigenic determinants (such as on viruses, cells or other materials), drugs, oligonucleotides, nucleic acids, peptides, cofactors, lectins, sugars, polysaccharides, cells, cellular membranes, and organelles. Column 6, line 65 – column 7, line column 7, line 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 123-129 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li, 6,704,104.

As to claim 123, while Li disclose that the probes may be different from each other (e.g., column 7, lines 13-33), there is no explicit disclosure of at least three different probes (claim 123) or at least ten different probes (claim 131). However, the skilled artisan would have recognized that the teachings of Li would allow for use of at least three or ten different probes. Given the teachings by Li on providing sufficient resolution of the detector and deconvolution techniques, for detection of high density arrays, the skilled artisan would have had reasonable expectation of success in using at least three or ten different probes [and labels] and in their detection.

As to claim 124, again, an exemplary embodiment is given in which the samples, taken at four different times, are labeled with four different dyes for simultaneous detection (column 14, lines 29-66). While the exemplary embodiment compares target quantity of the *same* target in the samples taken at four different time, the skilled artisan would have understood that the method can be modified to detect different probes in the four samples (detection using different probes is discussed in, for example, column 6, lines 50-59, and column 7, lines 13-33), as may be desirable for analyzing multiple analytes in the different samples conveniently at the same time.

As to claims 125 and 126, the second sample can be derived at a different point in time for comparison of the target quantity at the different points in time (column 14,lines 29-66). Li disclose that examples of probes that accommodated at an array of sites include agonists and antagonists for cell membrane receptors, toxins and

venoms, viral epitopes, hormones (e.g., opioid peptides, steroids, etc.), hormone receptors, peptides, enzymes, enzyme substrates, cofactors, drugs, lectins, sugars, oligonucleotides, nucleic acids, oligosaccharides, proteins, and monoclonal antibodies. Column 6, lines 50-59. It is also disclosed that examples of targets include antibodies, cell membrane receptors, monoclonal antibodies and antisera reactive with specific antigenic determinants (such as on viruses, cells or other materials), drugs, oligonucleotides, nucleic acids, peptides, cofactors, lectins, sugars, polysaccharides, cells, cellular membranes, and organelles. Column 6, line 65 – column 7, line column 7, line 12. A general example of drug testing is also disclosed (column 7, lines 34-47.)

Exposing a sample to another sample prior to detection with the probes is well known in the art as the skilled artisan would have recognized that such steps allow for determination of, for example, the effect of a drug or toxin [third sample], on a biological substance [e.g., second sample], and its effect [e.g., inhibition, modification] on the binding between the biological substance with the probe binding partner. Moreover, comparing such detection results to a detection in which the first sample is *not* exposed to the second sample is also well known in the art as the skilled artisan would have recognized that such steps provide for a negative control for comparison purposes and/or background noise consideration. Comparison to a reference is also discussed by Li in the background section (column 2, lines 52-56.)

As to claim 127, as discussed earlier, the probes can have different species (column 7, lines 13-33.)

As to claim 128, Li disclose in the embodiment in figures 11a and 11b, that four samples may correspond to the expression of a gene monitored at four different times. Column 14, lines 29-53. The skilled artisan would have recognized that the method can be used to analyze products of a cDNA library.

As to claim 129, Li disclose in the embodiment in figures 11a and 11b, that four samples may correspond to the expression of a gene monitored at four different times. Column 14, lines 29-53. In this exemplary embodiment, the targets are of the same type. However, as mentioned above, the skilled artisan would have recognized that the targets, and thus the probes, may be of different species for simultaneously detecting the different species. The skilled artisan would have recognized that the first sample and the second sample [for example, taken at a different point in time] can be exposed to the same types of probes for comparison study of the target analyte concentration at the different points in time, as suggested by Li.

As to claim 131, while Li disclose that the probes may be different from each other (e.g., column 7, lines 13-33), there is no explicit disclosure of at least ten different probes (claim 131). However, the skilled artisan would have recognized that the teachings of Li would allow for use of at least ten different probes. Given the teachings by Li on providing sufficient resolution of the detector and deconvolution techniques, for detection of high density arrays, the skilled artisan would have had reasonable expectation of success in using at least three or ten different probes [and labels] and in their detection.

Also, given that detection of concentration of a target is disclosed (e.g., column 7, lines 13-33), the skilled artisan would have recognized that the method encompass detection in which there are least two components in the sample that carry identical immobilized signaling entities (i.e., identical targets in the sample tagged with identical dyes), and can be modified for detection where there are at least ten target molecules that carry identical immobilized signaling entities (i.e., ten identical target in the sample tagged with identical dye).It is noted that there is no requirement that the components be different from each other.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs. 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641